AMENDMENTS TO THE CLAIMS

Please amend claim 37 and add new claims 62-65 below. The following listing of claims should replace previous claim listings.

Claim 1 (Original): A pharmaceutical composition of desloratadine comprising of a mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 25% to about 75% of either form to the other and a pharmaceutically acceptable excipient.

Claim 2 (Original): The pharmaceutical composition of claim 1, wherein the ratio is approximately 50%.

Claim 3 (Original): The pharmaceutical composition of claim 1, wherein the ratio is of about 55 to about 65% Form I to about 35 to about 45% of Form II.

Claim 4 (Original): The pharmaceutical composition of claim 1, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by DSC.

Claim 5 (Original): The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 1% by weight polymorphic change and chemical degradation after grinding for one minute.

Claim 6 (Original): The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 1% by weight chemical decomposition after storage at 100% relative humidity for one week.

Claim 7 (Original): The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 8 (Original): The pharmaceutical composition of claim 7, wherein the mixture used for composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 9 (Original): The pharmaceutical composition of claim 8, wherein the mixture used for composition undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 10 (Original): The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 11 (Original): The pharmaceutical composition of claim 10, wherein the mixture used for composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 12 (Original): The pharmaceutical composition of claim 11, wherein the mixture used for composition undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 13 (Original): The pharmaceutical composition of claim 1, wherein the mixture used for formulation complies with the GMP requirements.

Claim 14 (Withdrawn): A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 1 to the mammal in need thereof.

Claim 15 (Original): A pharmaceutical composition of desloratadine comprising of crystalline form desloratadine I and II in a weight to weight ratio of about 20% to about 40% of Form II and a pharmaceutically acceptable excipient.

Claim 16 (Original): The pharmaceutical composition of claim 15, wherein the Form II content of the mixture is about 24% to about 38%.

Claim 17 (Original): The pharmaceutical composition of claim 15, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by DSC.

Claim 18 (Original): The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 1% by weight polymorphic change and chemical degradation after grinding for one minute.

Claim 19 (Original): The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 1% by weight chemical decomposition after storage at 100% relative humidity for one week.

Claim 20 (Original): The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 21 (Original): The pharmaceutical composition of claim 20, wherein the composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 22 (Original): The pharmaceutical composition of claim 21, wherein the composition undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 23 (Original): The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 24 (Original): The pharmaceutical composition of claim 23, wherein the composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 25 (Original): The pharmaceutical composition of claim 24, wherein the composition undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 26 (Original): The pharmaceutical composition of claim 15, wherein the mixture complies with the GMP requirements.

Claim 27 (Withdrawn): A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 17 to the mammal in need thereof.

Claim 28 (Original): A stable mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 25% to about 75% of either form to the other, wherein the mixture is stable in that it undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 29 (Original): A stable mixture of crystalline form desloratadine in a weight to weight ratio of from about 20-40% Form II to about 60-80% Form I, wherein the mixture is stable in that it undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 30 (Original): The stable mixture of claim 29, wherein the weight to weight ratio is from about 24-38% Form II to about 62-76% form I.

Claim 31 (Previously Presented): The stable mixture of any of claims 28 or 29, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by DSC.

Claim 32 (Original): The stable mixture of claim 28 or 29, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 33 (Original): The stable mixture of claim 32, wherein the mixture undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 34 (Original): The stable mixture of any of claims 28 or 29, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 35 (Original): The stable mixture of claim 34, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 36 (Original): The stable mixture of claim 35, wherein the mixture undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 37 (Currently Amended): A stable mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 25% to about 75% of either form, prepared by a process comprising:

~~i)~~ a) combining desloratadine salt, toluene and a base to obtain a reaction mixture;

~~j)~~ b) heating the mixture, whereby two phases are obtained;

~~k)~~ c) separating the phases; l) concentrating the separated organic phase;

~~m)~~ d) dissolving the obtained concentrate in a toluene-2-propanol mixture containing less than about 20% 2-propanol by volume;

~~n)~~ e) cooling the solution to obtain a slurry;

~~o)~~ f) combining the slurry with cold n-heptane; and

~~p)~~ g) recovering the stable mixture ~~of desloratadine forms I and II~~.

Claim 38 (Original): The stable mixture of claim 37, wherein the process further comprises washing the product of step c with water.

Claim 39 (Original): The stable mixture of claim 37, wherein the process further comprises warming the product of step f to 45°C

Claim 40 (Original): The stable mixture of claim 37, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 41 (Original): The stable mixture of claim 40, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 42 (Original): The stable mixture of claim 41, wherein the mixture undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 43 (Original): The stable mixture of claim 37, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 44 (Original): The stable mixture of claim 43, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 45 (Original): The stable mixture of claim 44, wherein the mixture undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 46 (Original): The stable mixture of claim 37, wherein the mixture complies with the GMP requirements.

Claim 47 (Original): The stable mixture of claim 37, wherein the dissolution rate in vitro of the stable mixture, when measured by the U.S.P Paddle Method at 50-90 RPM in 900 mL water is not less than 80% (by weight) of the mixture released after 30 minutes.

Claim 48 (Original): A pharmaceutical formulation comprising the stable mixture of claim 37.

Claim 49 (Original): A pharmaceutical composition of desloratadine prepared by a process comprising the steps of:

a) preparing a mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 20% to about 40% Form II to Form I; and

b) combining the mixture with a pharmaceutically acceptable excipient to obtain a pharmaceutical composition.

Claim 50 (Original): The pharmaceutical composition of claim 49, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by DSC.

Claim 51 (Original): The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 1% by weight polymorphic change and chemical degradation after grinding for one minute.

Claim 52 (Original): The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 1% by weight chemical decomposition after storage at 100% relative humidity for one week.

Claim 53 (Original): The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 54 (Original): The pharmaceutical composition of claim 53, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 55 (Original): The pharmaceutical composition of claim 54, wherein the mixture undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

Claim 56 (Original): The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 57 (Original): The pharmaceutical composition of claim 56, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 58 (Original): The pharmaceutical composition of claim 57, wherein the mixture undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

Claim 59 (Original): The pharmaceutical composition of claim 49, wherein the mixture complies with the GMP requirements.

Claim 60 (Withdrawn): A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 49 to the mammal in need thereof.

Claim 61 (Previously Presented): The stable mixture of claim 37, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by DSC.

Claim 62 (New; Withdrawn): A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 15 to the mammal in need thereof.

Claim 63 (New): A pharmaceutical composition of desloratadine comprising the stable mixture of any of claims 28 or 29 and a pharmaceutically acceptable excipient.

Claim 64 (New; Withdrawn): A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 63 to the mammal in need thereof.

Claim 65 (New; Withdrawn): A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 48 to the mammal in need thereof.